

# PSJ3

## Exhibit 386

SUSC

January 31, 2008



- Review Anti-Trust and Anti-Harassment Policies
- Background
  - DEA SO requirements
  - HDMA BP's – efforts to date
- Legal and Policy Perspective
- Potential Best Practices; questions for Attendees
- Discussion; Member input
- “Model” modifications; areas for further review
- Next steps; additional DEA issues





require  
robotic



- Best Practices identified as a possible solution - 10/16/07 HDMA DEA Meeting
- Recommendation from Outside Counsel to move forward 12/19/07
- Request for members' existing BPs - 01/03/08
- Follow-up requests for copies and requests for "interviewees" - 01/07 through 01/11/08
- Presentation to Pain Coalition – 01/10/08
- Established a consulting contract with Wilson Security Services - 01/11/08
- Pharmacy Association Meeting (NACDS, APhA, NCPA) – 01/14/08
- Interviews – week of 01/21/08
- Review of first draft BP's 01/31/08



Desired Outcome: Agree upon fundamentals of distribution industry BP for Suspicious Orders for GPPC review; eventually provide to DEA

- To get there, we'll:
  - Review circulated draft & request your input
  - Reach agreement where we can
  - i.d., areas for further consideration





- Information gathering
  - Distributor requests information about the potential customers' background, customer base, credit, etc.
- Information review
  - distributor verifies completeness and reviews the information
- Investigation
  - Distributor seeks additional background information e.g, check Fed. Reg. for actions against potential customer



- **Background notes**

- Regulation's requirements
- Distinguish between order vs. sale
- i.d. "suspicious" upon order receipt

- **System design**

- i.d. product Characteristics; establish groups or "families" of drugs based on class of trade &/or product

- **Develop "Thresholds"**

- Calculate "average" orders for "families"
- Id. orders of "unusual" size/frequency/pattern

- **Stop shipments**





- **Designating an investigator(s)**
  - Experience, qualifications
- **Elements of the investigation**
  - Review prior orders for trends/discrepancies
  - Interview customer
  - Verify customer input
- **Documentation**
- **Shipment decisions**
  - Releasing/cancelling shipment process
  - 4 decision options



## Filing a SO Report

- Immediate vs. monthly
- Correspondence
  - Where/how to send
- Documentation

## Training and SOPs

- Training is recommended
- Written SOPs



## **Consider possible additions, e.g.,**

- Audits?
- Customer Accreditation program?
- DEA liaison?
- Questionable registrants?
- Written notices to DEA?
- Updating Customer information?







- GPPC Review— Feb. 12
- HDMA Exec. Committee Review - Feb. 22
- Request meeting with DEA Acting Administrator
  - Should the BP's become a regulation?
- Supply Chain Partner Best Practices (?)



- Guidance letter under internal DEA review
- Letter will say registration required – even for controlled substances registrants
- Distribution prior to obtaining registration





- Advisory being implemented
- Request for monthly eligible registrant list updates
  - DEA will consider the request
- Increases in 10 mgs







- Request the DEA develop/send ARCOS analysis of trends, for distributors to use to develop SO systems
  - By drug type
  - By state and/or region
- Have Pharmacies report Rx data
  - May have to be at state level
  - May require federal legislation
- Support a dual system – allow some orders to be filled but not others e.g.,
  - Clarify suspicious “transactions” vs. “orders” - allow certain transactions with reporting, but stop the SO’s

The logo for CHDMA, featuring a stylized 'C' and 'H' followed by the letters 'IDMA'.



- Enhance DEA and/or state pharmacy oversight
  - inspections
  - registration requirements (?)
- Suggest DEA support/develop a transaction review & exception process
  - Work with DEA to form criteria; better definitions; standards
  - Have DEA give “permission” to ship if criteria are met
- Legal challenge
  - May requires extensive justification, e.g., DEA changed a 30 year reporting requirement to stopping transactions

